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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/469,606	12/22/1999	HEINZ PETER VOLLMERS	PATWA-2	5150

21559 7590 08/26/2003

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/469,606

Applicant(s)

VOLLMERS ET AL.

Examiner

Alana M. Harris, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-37, 39, 40 and 42-44 is/are pending in the application.
- 4a) Of the above claim(s) 5-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1;3,4,39,40 and 42-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 5, 2003 has been entered.

2. Claims 1, 3-37, 39, 40 and 42-44 are pending.

Claims 5-37, drawn to non-elected inventions are withdrawn from consideration.

Claims 1, 4 and 39 have been amended.

Claims 38 and 41 have been cancelled.

Claims 42-44 have been added.

Claims 1, 3, 4, 39, 40 and 42-44 are examined on the merits.

Withdrawn Rejections

Claim Rejections - 35 USC § 102

3. The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Medof et al. (J. Exp. Med. 160:1558-1578, 1984), as evidence by Hensel et al. (Cancer Res. 59:5299-5306, October 15, 1999/ reference AV on IDS) is withdrawn in light of the amendment to claim 1.

Art Unit: 1642

4. The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Tsuji (U.S. Patent number 5,695,945, issued December 9, 1997), as evidence by Hensel et al. (Cancer Res. 59:5299-5306, October 15, 1999/ reference AV on IDS) is withdrawn in light of the amendment to claim 1.

Maintained and New Grounds of Rejection

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **THIS IS A NEW MATTER REJECTION.**

Applicants have amended claim 1 to included the recitation, "wherein said glycoprotein is present on a stomach carcinoma cell, but not on a normal cell".

Applicants also state in the Remarks received June 5, 2003 as Paper number 29 that support for this amendment can be found in the specification at page 3, line 25-page 4, line 5. The Examiner has reviewed this section of the disclosure. This section is not commensurate with the claim amendment. On lines 25-27 of page 3 it is stated that "[t]he cellular receptor [or glycoprotein] is an isoform of the protein CD55/DAF that is

Art Unit: 1642

specific for tumor cells, especially for gastric carcinoma cells". This statement implies that the referenced cellular receptor is one of many isoforms of CD55/DAF and not necessarily the claimed glycoprotein. Moreover, lines 26 and 27 state CD55/DAF is specific for tumors, especially for gastric carcinoma cells, whereas the claim distinctly states stomach carcinoma cell. The passage from the specification does not preclude or limit other carcinomas or cancer cells. Hence, this passage does not fully support Applicants' claim amendment. Applicants are requested to remove the new matter or provide proper support for the amendment to claim 1. If the proper support is not supplied and the amendment is deleted the art rejections of the Final office action mailed August 27, 2002 as Paper number 18 will be reinstated.

7. Claims 1, 3, 4, 39, 40 and 42-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants broadly claim an isolated glycoprotein that comprises at least one section of the amino acid primary structure of CD55, a tumor-specific glycostructure and the glycoprotein is naturally-occurring. However, Applicants have not assigned a sequence identifying number to the protein, nor described the structure or the section of the amino acid that supports the activity of the protein. Applicants are not entitled to all proteins capable of exhibiting this structure or containing the amino acid primary

Art Unit: 1642

structure of CD55. Applicant is only in possession of one species, which is not identified by a sequence identity number or explicitly defined by structure. The specification does provide details of the glycoprotein such as the 82kD molecular weight of the protein and that it must be reactive with antibody, SC-1 as stated in the claims (see page 5, first full paragraph). But as claim 1 reads it also encompasses a glycoprotein that may be a variant containing deletions, insertions and/or substitutions as further exemplified in the said section of the specification. Applicants are not permitted to claim all proteins that are encompassed by the claims, hence not entitled to the wide breadth of the claims at issue.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 115).

With the exception of the glycoprotein defined by its molecular weight and the monoclonal antibody that binds it, the skilled artisan cannot envision the detailed structure of the encompassed polypeptides and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement

Art Unit: 1642

that it is part of the invention and a reference to a potential method of isolating it. The polypeptide itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

There is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

The full breadth of the claims does not meet the written description provision of 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1642

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 43 is rejected under 35 U.S.C. 102(b) as being anticipated by Medof et al.

(J. Exp. Med. 160:1558-1578, 1984), as evidenced by Hensel et al. (Cancer Res. 59:5299-5306, October 15, 1999/ reference AV on IDS). Medof discloses a purified DAF that is the same as CD55 as established by Hensel. This purified DAF is associated with the red cell membrane, see bridging sentence of pages 1558 and 1559; page 1562, first sentence of second full paragraph. Inherently, this disclosed protein has at least one section of the human amino acid primary structure of CD55 and a tumor-specific glycostructure, wherein if present on a cell and bound by an antibody that is specific for said glycostructure would result in apoptosis of said cell.

10. Claim 43 is rejected under 35 U.S.C. 102(b) as being anticipated by Tsuji (U.S. Patent number 5,695,945, issued December 9, 1997), as evidenced by Hensel et al. (Cancer Res. 59:5299-5306, October 15, 1999/ reference AV on IDS).

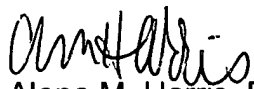
Tsuji discloses a purified DAF that is the same as CD55 as established by Hensel. Human DAF molecules were purified from erythrocyte membrane, see column 2, lines 6 and 7. Inherently, this disclosed protein has at least one section of the human amino acid primary structure of CD55 and a tumor-specific glycostructure, wherein if present on a cell and bound by an antibody that is specific for said glycostructure would result in apoptosis of said cell.

Art Unit: 1642

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 7:00 am to 4:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.


Alana M. Harris, Ph.D.
August 25, 2003